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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

18-JAN-2000

OFFICE OF
PREVENTION, PESTICIDES AND
TOXIC SUBSTANCES

MEMORANDUM

SUBJECT: Glyphosate on Various Commodities. IR-4 Proposal For Tolerance Translations for a Variety of Minor Crops.

DP Barcode: D262424
Chemical#: 417300
Class: herbicide
40 CFR 180.364

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REQUEST

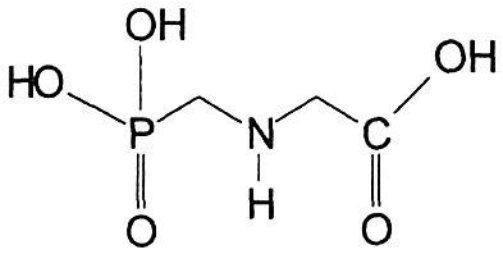
The Interregional Research Project No. 4 (IR-4) has proposed a set of tolerance translations for the active ingredient glyphosate based on its low toxicity and crop use patterns. IR-4 wishes to expand the scope of crops for which glyphosate is registered/has tolerances by making use of the existing glyphosate residue chemistry database.

BACKGROUND

Glyphosate (N-phosphonomethyl glycine) is a nonselective herbicide and plant growth regulator that includes the isopropylamine salt (chemical code 103601), the sesquisodium salt (103603), the ammonium salt (103604), the ethanolamine salt (103605), and the acid (417300).

Glyphosate is typically applied as a postemergence spray to foliage of the vegetation controlled before planting, after planting but prior to crops emergence, as a directed spray in established crops, or directly to crops as in over-the-top application to glyphosate resistant canola. In addition, glyphosate may be used in and around aquatic sites; treated water from aquatic sites may be used to irrigate crops (Source: LUIS General Chemical Draft Report for Glyphosate, 7/20/92).

Tolerances for residues of glyphosate (180.364) in or on food/feed and in processed commodities are expressed in terms of parent glyphosate only resulting from the application of the isopropylamine or ammonium salt forms of glyphosate or glyphosate, acid to a wide variety of raw agricultural commodities. The structure of the acid form of glyphosate is shown below:



Toxicity

Glyphosate exhibits low mammalian toxicity. No acute dietary or short-, intermediate-, or chronic-term dermal or inhalation toxicity endpoints were identified in the HIARC meeting held on 26-MAR-1998. The Health Effects Division Carcinogenicity Peer Review Committee concluded that glyphosate should be classified as Group E (evidence of non-carcinogenicity for humans), based upon lack of convincing carcinogenicity evidence in adequate studies in two animal species (26-JUN-1991). The chronic dietary endpoint for glyphosate comes from the developmental study in rabbits and is based on the occurrence of diarrhea, nasal discharge, and death at 350 mg/kg/day (LOAEL), with a NOAEL of 175 mg/kg/day. The FQPA Safety Factor Committee determined that the 10X factor to account for enhanced sensitivity of infants and children (as required by FQPA) should be removed (memo, B. Tarplee and J. Rowland, 17-APR-1998). Thus, using an uncertainty factor of 100 in conjunction with the NOAEL of 175 mg/kg/day gives a Population Adjusted Dose (PAD) of 2.0 mg/kg/day.

Residue Chemistry

The nature of the residue in plants and animals is adequately understood based on metabolism studies on corn, cotton, soybeans, wheat, goats, and hens (R. Perfetti, 27-SEP-1992). The HED Metabolism Committee determined that only glyphosate parent is to be regulated in

plant and animal commodities, and that the major metabolite, AMPA (aminomethyl phosphonic acid) is not of toxicological concern regardless of its level in food (see Metabolism Committee Memo, R. Perfetti, 17-MAR-1994).

For the current petition, separate use directions are specified for orchard type crops and other food crops. For orchard type crops, the instructions allow preplant (site preparation), strips (in row), chemical mowing (growth suppression), and middles (between rows). The directions emphasize that extreme care must be taken to ensure no part of the tree is contacted by herbicide solution, spray drift, or mist. For other food crops, the instructions allow chemical fallow, preplant fallow beds, preplant, preemergence, post-directed hooded, and postharvest applications. Preplant applications must be made at least 3 days prior to transplanting. The preemergence application must be made prior to the emergence of the crop. Post-directed hooded applications are applied to mulched or unmulched row middles after crop establishment and must be made at least 14 days prior to harvest. Postharvest applications may be applied after the final harvest to control weeds or suppress regrowth of annual crops or for renovation of biennial or perennial crops beds, and must be made at least 14 days prior to planting the next crop. Treated vegetation may not be harvested or fed to animals.

HED COMMENTS/CONCLUSIONS

Due to the low toxicity of glyphosate (no acute dietary, cancer, or short-, intermediate-, or chronic-term dermal or inhalation endpoints were identified), removal of the FQPA factor, the plant-growth regulating action of glyphosate, and the extensive existing database on glyphosate, **HED agrees to the data translations listed in Tables 1 and 2 FOR GLYPHOSATE ONLY. HED emphasizes that the use rates and PHIs between the proposed crops and those being used for data translation must be similar.**

DETAILED CONSIDERATIONS

Crop Group 19 - Herbs and Spices group

Proposal

The registrant has not submitted any field trial data from crop group 19 to the Agency. IR-4 proposes that EPA establish a 2.0 ppm tolerance for herbs and spices based on the established 0.2 ppm tolerance on leafy vegetables (except Brassica) group (Crop Group 4) divided by the percent dry matter (%DM) for fresh basil (10%). The dry down factors utilized for basil and all the commodities as needed in this memo were taken from Dr. Bernie Scheider's memo to W. Donovan entitled "Glyphosate IR-4 Chemistry Draft Dry Down Factors", 22-OCT-1999.

HED's Comments/Conclusions

The EPA Series 860 residue chemistry guidelines specify a total of 12 field trials (3 each for basil (fresh and dried), chive, dill seed or celery seed, and black pepper) in order to establish a tolerance for the herbs and spices crop group. Although no glyphosate residue data are available for any of the representative commodities of the herbs and spices crop group, HED is willing to derive a crop group 19 tolerance by translating the existing glyphosate tolerance from crop group 4 (leafy vegetables (except Brassica)) using the fresh basil percent dry matter as a correction factor to account for drying. However, HED emphasizes that this approach is acceptable FOR GLYPHOSATE ONLY, and is based on the low toxicity of glyphosate, the extensive existing glyphosate database, the plant-growth regulating action of glyphosate, and the relatively low consumption of herbs and spices.

Miscellaneous Crops

IR-4 also proposes that EPA establish the proposed tolerances listed in Tables 1 and 2 for miscellaneous crops, based on data translations for similar crops. Table 1 shows calculation of proposed tolerances making use of the existing leafy vegetable tolerance together with a correction factor for percent dry matter, while Table 2 includes those crops whose drying (if any) is accounted for by the translation crop.

Table 1. Proposed tolerances for commodities whose drying (if any) is not accounted for by the translation crop.

Raw Agricultural Commodity (RAC)	%DM	Translation crop(s)	Translation crop tolerance (ppm)	Proposed Tolerance[1] (ppm)
chaya	20	leafy vegetables	0.2	1.0
dokudami	10	leafy vegetables	0.2	2.0
epazote	16	leafy vegetables	0.2	1.3
oregano, mexican, leaves	10	leafy vegetables	0.2	2.0
perilla, tops	11	leafy vegetables	0.2	1.8

[1] Calculated as [Translation tolerance]/[%DM].

Table 2. Proposed tolerance levels for crops whose drying (if any) is accounted for by the translation crop.

Raw Agricultural Commodity (RAC)	Translation crop(s)	Translation crop tolerance (ppm)	Proposed tolerance (ppm)
ambarella	guava	0.2	0.2
blimbe	guava	0.2	0.2
imbu	guava	0.2	0.2
rose apple	guava	0.2	0.2
surinam cherry	guava	0.2	0.2
biriba	sugar apple	0.2	0.2
ilama	sugar apple	0.2	0.2
imbe	sugar apple	0.2	0.2
pawpaw	sugar apple	0.2	0.2
governor's plum	papaya	0.2	0.2
mamey apple	papaya	0.2	0.2
papaya, mountain	papaya	0.2	0.2
aloe vera	cucurbit vegetables	0.5	0.5
cactus, fruit	cucurbit vegetables	0.5	0.5
cactus, pads	cucurbit vegetables	0.5	0.5
nut, pine	tree nuts	1.0	1.0
betelnut	tree nuts	1.0	1.0
pistachio*	tree nuts	1.0	1.0
stevia, dried leaves	dried tea	1.0	1.0
ugli fruit	citrus fruits	0.5	0.5
crambe, seed	sunflower seed	0.1	0.1
flax, seed	sunflower seed	0.1	0.1
mustard, seed	sunflower seed	0.1	0.1

Raw Agricultural Commodity (RAC)	Translation crop(s)	Translation crop tolerance (ppm)	Proposed tolerance (ppm)
rapeseed, seed	sunflower seed	0.1	0.1
safflower, seed	sunflower seed	0.1	0.1
borage, seed	sunflower seed	0.1	0.1
gourd, buffalo, seed	sunflower seed	0.1	0.1
jojoba, seed	sunflower seed	0.1	0.1
lesquerella, seed	sunflower seed	0.1	0.1
meadowfoam, seed	sunflower seed	0.1	0.1
sesame, seed	sunflower seed	0.1	0.1
artichoke, globe	brassica (cole) leafy vegetables	0.2	0.2
bamboo, shoots	brassica (cole) leafy vegetables	0.2	0.2
palm heart, leaves	brassica (cole) leafy vegetables	0.2	0.2
kava, roots	carrot, potato, radish	0.2	0.2
galangal, roots	carrot, potato, radish	0.2	0.2
ginger, white, flower	leafy vegetable	0.2	0.2
wasabi, roots	carrot, potato, radish	0.2	0.2
yacon, tuber	carrot, potato, radish	0.2	0.2
gow kee, leaves	leafy vegetables	0.2	0.2
mioga, flower	leafy vegetables	0.2	0.2
pepper leaf, fresh leaves	leafy vegetables	0.2	0.2
ti, leaves	leafy vegetables	0.2	0.2
ti, roots	carrot, potato, radish	0.2	0.2

Raw Agricultural Commodity (RAC)	Translation crop(s)	Translation crop tolerance (ppm)	Proposed tolerance (ppm)
water spinach, tops	leafy vegetables	0.2	0.2
watercress, upland	leafy vegetables	0.2	0.2
hops cones, dried	instant tea	7.0	7.0
juneberry	berry group	0.2	0.2
lingonberry	berry group	0.2	0.2
salal	berry group	0.2	0.2
kenaf, forage	nongrass animal feed group	200	200
leucaena, forage	nongrass animal feed group	200	200
okra	fruiting vegetables (except cucurbits)	0.1	0.1
quinoa, grain	wheat grain	5.0	5.0
teff, grain	wheat grain	5.0	5.0

* Pistachio already has a tolerance of 0.2 ppm for glyphosate residues. The current proposal to increase this level to 1.0 ppm is intended to harmonize the pistachio tolerance with that of the tree nut crop group.

HED's Comments/Conclusions

The EPA Series 860 residue chemistry guidelines specify a minimum of 5 field trials for flax, safflower, and okra; 3 field trials for hops, sesame, and rapeseed; and one field trial for all the other crops listed in Tables 1 and 2 (assuming <200 total acres growth) as being needed to establish appropriate tolerances. Although no glyphosate residue data are available for any of the crops listed in Tables 1 and 2, HED recommends for establishment of the tolerances listed in Tables 1 and 2, since these values take drying into account. However, HED emphasizes that this approach is acceptable FOR GLYPHOSATE ONLY, and is based on the low toxicity of glyphosate, the extensive existing glyphosate database, the plant-growth regulating action of glyphosate, and the relatively low consumption of the commodities listed in Tables 1 and 2.

cc: RAB1 Reading File, W. Donovan, B. Schneider
RDI: G. Kramer (10-NOV-1999), RAB1 Chemists (10-NOV-1999), ChemSAC (12-JAN-2000)
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